4,344,949 #25

Roche Biomedical Laboratories, Inc., 1912 Alexander Drive, P.O. Box 13973, Research Triangle Park, NC 27709, 919-361-7770.
Roche Biomedical Laboratories, Inc., 69 First Avenue, Raritan, NJ 08869, 800-437-4986.
Roche Biomedical Laboratories, Inc., 1120 Stateline Road, Southaven, MS 38671 601-342-1286.
Scott & White Drug Testing Laboratory, 600 South 25th Street, Temple, TX 76504, 800-749-3788.
S.E.D. Medical Laboratories, 500 Walter NE suite 500, Albuquerque, NM 87102, 505-848-8800.
Sierra Nevada Laboratories, Inc., 888 Willow Street, Reno, NV 89502, 800-648-5472.
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Avenue, Van Nuys, CA 91045, 818-378-2520.
SmithKline Beecham Clinical Laboratories, 3175 Presidential Drive, Atlanta, GA 30340, 404-934-9205. (name changed: formerly SmithKline Bio—Science Laboratories).
SmithKline Beecham Clinical Laboratories, 506 E. State Parkway, Schaumburgh, IL 60173, 708-885-2010. (name changed: formerly International Toxicology Laboratories).
SmithKline Beecham Clinical Laboratories, 11636 Administration Drive, St. Louis, MO 63146, 314-567-3905.
SmithKline Beecham Clinical Laboratories, 400 Egypt Road, Norristown, PA 19403, 800-523-5447 (named changed: formerly SmithKline Bio-Science Laboratories).
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214-638-1301 (name changed: formerly Smith Kline Bio-Science Laboratories).
South Bend Medical Foundation, Inc., 530 North Lafayette Boulevard, South Bend, IN 46601, 219-234-4176.
Southgate Medical Services, Inc., 21100 Southgate Park Boulevard, Cleveland, OH 44137-3054, 800-338-0166 (outside OH) / 800-362-6913 (inside OH) (name changed: formerly Southgate Medical Laboratory).
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 North Lee Street, Oklahoma City, OK 73102, 405-272-7052.
St. Louis University Forensic Toxicology Laboratory, 1205 Carr Lane, St. Louis, MO 63104, 314-577-8628.
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, suite 208, Columbia, MO 65203, 314-882-1273.
Toxicology Testing Service, Inc., 5426 NW. 79th Avenue, Miami, FL 33166, 305-593-2260.

Richard A. Millstein,

Acting Director, National Institute on Drug Abuse.

[FR Doc. 92-2744 Filed 2-3-92; 8:45 am]

BILLING CODE 4160-20-M

Food and Drug Administration

[Docket No. 91E-0492]

Determination of Regulatory Review Period for Purposes of Patent Extension; Accupril®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Accupril® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health affairs (HFY-20), Food and Drug Administration, 5600 Fisher Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g) (1)(B).

FDA recently approved for marketing the human drug product Accupril®. Accupril® (quinapril hydrochloride) is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Accupril® (U.S. Patent No. 4,344,949) from Warner-Lambert Co., and the Petent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated December 20, 1991, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Accupril® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Accupril® is 3,441 days. Of this time, 2,414 days occurred during the testing phase of the regulatory review period, while 1,027 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: June 18, 1982. FDA has verified the applicant's claim that the date the investigational new drug application became effective was June 18, 1982.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: January 26, 1989. FDA has verified the applicant's claim that the new drug application (NDA) for Accupril® (NDA 19-885) was filed on January 26, 1989.

3. The date the application was approved: November 19, 1991. FDA has verified the applicant's claim that NDA 19-885 was approved on November 19, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2,204 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 6, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 3, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 28, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 92-2633 Filed 2-3-92; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Meeting

Notice is hereby given that the Office of Research on Women's Health (ORWH) in the Office of the Director, National Institutes of Health, will hold a public hearing on March 2 and 3, 1992, from 8 a.m. to 4:30 p.m., in Wilson Hall, Building 1, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The purpose of this hearing is to accept public testimony from individuals and organizations interested in the subject of recruitment, retention, re-entry, and advancement of women in biomedical careers.

This testimony will be used to help the members of the ORWH Planning Task Force on Women in Biomedical Careers (the Task Force) to frame the issues and develop the agenda for an ORWH-sponsored workshop to formulate recommendations to increase the recruitment, retention, re-entry, and advancement of women in biomedical careers to be held on June 11 and 12, 1992, in Bethesda, Maryland. Task Force members will be present at the public hearing to accept testimony.

The number of women admitted to health professional schools and into doctoral and post-doctoral programs is increasing. Yet, the numbers of women in leadership positions in biomedical careers (such as tenured professors, department chairs, deans, senior scientists, and principle investigators) is not commensurate.

Barriers to entry and advancement continue to exist. Training grants and fellowships often do not take into account a woman scientist's family responsibilities and assumption of non-traditional roles, which often occur at crucial times in her scientific career. Minority women, in particular, often are not presented with opportunities to prepare themselves for scientific and/or academic careers during critical stages in their education. The "glass ceiling" effect, a situation where women are promoted to within close proximity of major leadership positions but infrequently attain these positions, continues unabated. New ways to retain and advance women in these careers must be identified and implemented.

All sessions are open to the public. However, seating is limited and will be on a first-come, first-served basis. Testimony for the public hearing should be confined to comments relating to recruitment, retention, re-entry, and advancement of women in biomedical careers. Due to time constraints, only *one* representative from each organization will be allowed to present oral testimony. Each presentation must be limited to 5 to 7 minutes.

A letter of intent to present such testimony should be sent by interested individuals and organizations to the attention of Ms. Margaret Pickerel of Prospect Associates, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852. The letter of intent to present testimony must be received by Prospect Associates no later than 5 p.m. (EST) on February 17, 1992. The date and time at which the letter of intent is received at Prospect Associates will establish the order of presentation at the March meeting.

Presenters should send three (3) written copies of their testimony, including a brief description of their organization, to the above address, no later than 5 p.m. (EST) on February 24, 1992. Written testimony received after that date and time will be accepted, but may not be included in the materials available to the Task Force members at the March 2 and 3, 1992, hearing.

Organizations wishing to provide only written statements may send three (3) copies of their statements to the above address by February 24th, 1992, no later than 5 p.m. (EST). All written testimony received by that date will be made available to Task Force members prior to the March meeting. Testimony received after that date will be sent to the Task Force, but may not be available at the March meeting.

For additional information contact Ms. [redacted] of Prospect Associates, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852, 301-468-2662, 301-770-5184 (FAX).

Dated: January 28, 1992.

Bernadine Healy,

Director, NIH.

[FR Doc. 92-2564 Filed 2-3-92; 8:45 am]

BILLING CODE 4140-01-M

Social Security Administration

Rescission of Social Security Ruling 69–33c Child's Insurance Benefits—Full Time Attendance at Evening High School—20-Hour Per Week Requirement

AGENCY: Social Security Administration, HHS.

ACTION: Notice of rescission of Social Security Ruling (SSR) 69–33c.

SUMMARY: The Commissioner of Social Security gives notice of the Rescission of SSR 69–33c Child's Insurance Benefits—Full-Time Attendance at Evening High School—20-Hour Per Week Requirement.

EFFECTIVE DATE: February 4, 1992.

FOR FURTHER INFORMATION CONTACT: Joanne K. Castelo, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1711.

SUPPLEMENTARY INFORMATION: Social Security rulings make available to the public precedential decisions relating to the Federal Old-Age, Survivors, Disability, Supplemental Security Income, and Black Lung Benefits Programs. Social Security rulings may be based on case decisions made at all administrative levels of adjudication, Federal court decisions, Commissioner's decisions, opinions of the Office of the General Counsel, and other policy interpretations of the law and regulations.

SSR 69–33c was published in the 1966–1970 Cumulative Edition of the Rulings. This Ruling concerns a claimant who was enrolled in an evening high school program at a fully accredited private school that enabled her to take 16½ hours of class per week. The school considered this scheduled attendance to be the equivalent of full-time day instruction under its standards and practices. However, SSR 69–33c held that, since the claimant's scheduled attendance was at the rate of less than 20 hours per week (a strict 20 hours of attendance per week requirement was mandated by the regulation then in effect), the claimant did not meet the